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74333US Express Mail Label N .: EJ Date f Deposit: February 29, 2000

Attorney Docket No. 15966-534C CIP1 (CURA-34C CIP1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:

Shimkets and Leach

ASSIGNEE:

CuraGen Corporation

SERIAL NUMBER:

09/472,688

FILING DATE:

December 27, 1999

For:

NUCLEIC ACIDS CONTAINING SINGLE NUCLEOTIDE POLYMORPHISMS AND

INER:

METHODS OF USE THEREOF

February 29, 2000 Boston, Massachusetts

Not Yet Assigned

Not Yet Assigned

TECH CENTER 1600

Assistant Commissioner for Patents Washington, D.C. 20231

TRANSMITTAL LETTER

Sir:

Transmitted herewith for filing in the present application are the following documents:

Information Disclosure Statement (4 pages);

Modified Form 1449/PTO duplicate copy (2 pages);

Copies of Cited references: A1, B1-B8, C1-C25; and

Return Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at 617/542-6000, Boston, Massachusetts.

No fee is believed to be due. However, if any fees are to be assessed, the Commissioner is hereby authorized to charge the balance due to the undersigned's account, Deposit Account No. 50-0311 (Reference 15966-534C CIP1, CURA-34C CIP1). A duplicate copy of this transmittal letter is enclosed.

Respectfully submitted,

Ivor R. Elrifi, Reg. No. 39,529

Shelby J. Walker, Reg. No. 45,192

Attorneys for Applicant

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TRADOCS:1299252.1(R%\$C01!.DOC)



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Assistant Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed below and on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are submitted herewith. The order of presentation of the references should not be construed as an indication of the importance of the references.

U.S. Patent Documents:

Affymetrix, Inc.	5,856,104

Foreign Patent Documents:

Affymax Technologies, N.V.	EP 717,113 A2	- <i>v</i>
Affymax Technologies, N.V.	WO 95/11995	
Trustees of Dartmouth College	WO 93/22456	V /
Genetics Institute, Inc.	WO 98/14470	
Lander, et al.	WO 98/20165	
Affymetrix, Inc.	WO 98/56954	
Progentior, Inc.	WO 8/14466	
Affymetrix, Inc.	WO 97/29212	

U.S.S.N.: 09/472,688



Other Prior Art - Non Patent Literature Documents:

Abravaya, K., J. J. Carrino, et al. (1995). "Detection of point mutations with a modified ligase chain reaction (Gap-LCR)." Nucleic Acids Res 23(4): 675-82.

Adams, M. D., J. M. Kelley, et al. (1991). "Complementary DNA sequencing: expressed sequence tags and human genome project." Science 252(5013): 1651-6.

Barany, F. (1991). "Genetic disease detection and DNA amplification using cloned thermostable ligase." Proc Natl Acad Sci U S A 88(1): 189-93.

Cotton, R. G., N. R. Rodrigues, et al. (1988). "Reactivity of cytosine and thymine in single-base-pair mismatches with hydroxylamine and osmium tetroxide and its application to the study of mutations." Proc Natl Acad Sci U S A 85(12): 4397-401.

Evans, W. E. and M. V. Relling (1999). "Pharmacogenomics: translating functional genomics into rational therapeutics." <u>Science</u> 286(5439): 487-91.

Faham, M. and D. R. Cox (1995). "A novel in vivo method to detect DNA sequence variation." Genome Res 5(5): 474-82.

Fischer, S. G. and L. S. Lerman (1983). "DNA fragments differing by single base-pair substitutions are separated in denaturing gradient gels: correspondence with melting theory." Proc Natl Acad Sci U S A 80(6): 1579-83.

Gibbs, R. A., P. N. Nguyen, et al. (1989). "Detection of single DNA base differences by competitive oligonucleotide priming." <u>Nucleic Acids Res</u> 17(7): 2437-48.

Kren, B. T., B. Parashar, et al. (1999). "Correction of the UDP-glucuronosyltransferase gene defect in the gunn rat model of crigler-najjar syndrome type I with a chimeric oligonucleotide." <u>Proc Natl Acad Sci U S A</u> 96(18): 10349-54.

Landegren, U., R. Kaiser, et al. (1988). "A ligase-mediated gene detection technique." <u>Science</u> 241(4869): 1077-80.

Maskos, U. and E. M. Southern (1993). "A novel method for the parallel analysis of multiple mutations in multiple samples." <u>Nucleic Acids Res</u> 21(9): 2269-70.

Myers, R. M., Z. Larin, et al. (1985). "Detection of single base substitutions by ribonuclease cleavage at mismatches in RNA:DNA duplexes." <u>Science</u> 230(4731): 1242-6.

Newton, C. R., A. Graham, et al. (1989). "Analysis of any point mutation in DNA. The amplification refractory mutation system (ARMS)." Nucleic Acids Res 17(7): 2503-16.

Nikiforov, T. T., R. B. Rendle, et al. (1994). "Genetic Bit Analysis: a solid phase method for typing single nucleotide polymorphisms." <u>Nucleic Acids Res</u> 22(20): 4167-75.

Orita, M., Y. Suzuki, et al. (1989). "Rapid and sensitive detection of point mutations and DNA polymorphisms using the polymerase chain reaction." Genomics 5(4): 874-9.

Orita, M., H. Iwahana, et al. (1989). "Detection of polymorphisms of human DNA by gel electrophoresis as single-strand conformation polymorphisms." Proc Natl Acad Sci U S A 86(8): 2766-70.

Orum, H., P. E. Nielsen, et al. (1993). "Single base pair mutation analysis by PNA directed PCR clamping." <u>Nucleic Acids Res</u> 21(23): 5332-6.

Rhodes, M., R. Straw, et al. (1998). "A high-resolution microsatellite map of the mouse genome." Genome Res 8(5): 531-42.

Saiki, R. K., P. S. Walsh, et al. (1989). "Genetic analysis of amplified DNA with immobilized sequence-specific oligonucleotide probes." Proc Natl Acad Sci U S A 86(16): 6230-4.

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Taillon-Miller, P., Z. Gu, et al. (1998). "Overlapping genomic sequences: A treasure trove of single-nucleotide polymorphisms [In Process Citation]." Genome Res 8(7): 748-54.

Thiede, C., E. Bayerdorffer, et al. (1996). "Simple and sensitive detection of mutations in the ras protooncogenes using PNA-mediated PCR clamping." Nucleic Acids Res 24(5): 983-4. **APPLICANTS:**

Shimkets !

U.S.S.N.:

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Wagner, R., P. Debbie, et al. (1995). "Mutation detection using immobilized mismatch binding protein (MutS)." Nucleic Acids Res 23(19): 3944-8.

Wallace, R. B., J. Shaffer, et al. (1979). "Hybridization of synthetic oligodeoxyribonucleotides to phi chi 174 DNA: the effect of single base pair mismatch." Nucleic Acids Res 6(11): 3543-57.

Youil, R., B. W. Kemper, et al. (1995). "Screening for mutations by enzyme mismatch cleavage with T4 endonuclease VII." Proc Natl Acad Sci U S A 92(1): 87-91.



This Information Disclosure Statement is being been filed: within three months of the filing date of the National Application; within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International Application; or before the mailing date of a first Office Action on the merits in the above-identified case. M Accordingly, no fee or certification is required. 37 C.F.R. §1.97

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached Form PTO-1449 (modified). It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and signs the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

APPLICANTS:

Shimkets Leach

U.S.S.N.:

09/472,688

Notwithstanding any statements by the Applicant, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested. Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 15966-534C CIP1 (CURA-34C CIP1).

FEB 2 9 2000 33

Respectfully submitted,

Ivor R. Elrifi, Reg. No. 39,529

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Dated: February 29, 2000

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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Modified Form 1449/PTO	Application Number	09/472,688
	Filing Date	12/27/99
INFORMATION DISCLOSURE	First Named Inventor	Shimkets
STATEMENT BY APPLICANT	Group Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
(use as many sheets as necessary)	Attorney Docket Number	15966-534C CIP1 (CURA-34C CIP1)

	1			U.S. PATENT DOCUMENTS			
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
	A1	5,856,104		Affymetrix, Inc.			

				FOREIGN PATENT DOCUMENTS			
Exam Initials	Cite No.	Foreign Patent Document Office Number		Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No	
	B1	EP	717,113 A2	Affymax Technologies, N.V.	19/06/96	x .	
	B2	wo	95/11995	Affymax Technologies, N.V.	04/05/95	x	
	В3	wo	93/22456	Trustees of Dartmouth College	11/11/93	×	
	B4	wo	98/14470	Genetics Institute, Inc.	09/04/98	x	
	B5	wo	98/20165	Lander, et al.	14/05/98	×	
	В6	wo	98/56954	Affymetrix, Inc.	17/12/98	x	
	B7	wo	98/14466	Progentior, Inc.	09/04/98	×	
	В8	wo	97/29212	Affymetrix, Inc.	14/08/97	×	

	0 - 1	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
	C1	Abravaya, K., J. J. Carrino, et al. (1995). "Detection of point mutations with a modified ligase chain
		reaction (Gap- LCR)." Nucleic Acids Res 23(4): 675-82.
	C2	Adams, M. D., J. M. Kelley, et al. (1991). "Complementary DNA sequencing: expressed sequence
		tags and human genome project." Science 252(5013): 1651-6.
	C3	Barany, F. (1991). "Genetic disease detection and DNA amplification using cloned thermostable
		ligase." Proc Natl Acad Sci U S A 88(1): 189-93.
	C4	Cotton, R. G., N. R. Rodrigues, et al. (1988). "Reactivity of cytosine and thymine in single-base-pair
		mismatches with hydroxylamine and osmium tetroxide and its application to the study of mutations."
		Proc Natl Acad Sci U S A 85(12): 4397-401.
	C5	Evans, W. E. and M. V. Relling (1999). "Pharmacogenomics: translating functional genomics into
		rational therapeutics." Science 286(5439): 487-91.
	C6	Faham, M. and D. R. Cox (1995). "A novel in vivo method to detect DNA sequence variation."
<u> </u>		<u>Genome Res</u> 5(5): 474-82.
	C7	Fischer, S. G. and L. S. Lerman (1983). "DNA fragments differing by single base-pair substitutions
		are separated in denaturing gradient gels: correspondence with melting theory." Proc Natl Acad Sci U
		<u>S A</u> 80(6): 1579-83.

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OTHER PRIOR ART COMPRESENT LITERATURE DOCUMENTS				
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.		
-	C8	Gibbs, R. A., P. N. Nguyen, et al. (1989). "Detection of single DNA base differences by competitive oligonucleotide priming." Nucleic Acids Res 17(7): 2437-48.		
	C9	Kren, B. T., B. Parashar, et al. (1999). "Correction of the UDP-glucuronosyltransferase gene defect in the gunn rat model of crigler-najjar syndrome type I with a chimeric oligonucleotide." Proc Natl Acad Sci USA 96(18): 10349-54.		
	C10	Landegren, U., R. Kaiser, et al. (1988). "A ligase-mediated gene detection technique." Science 241(4869): 1077-80.		
	C11	Maskos, U. and E. M. Southern (1993). "A novel method for the parallel analysis of multiple mutations in multiple samples." <u>Nucleic Acids Res</u> 21(9): 2269-70.		
	C12	Myers, R. M., Z. Larin, et al. (1985). "Detection of single base substitutions by ribonuclease cleavage at mismatches in RNA:DNA duplexes." Science 230(4731): 1242-6.		
	C13	Newton, C. R., A. Graham, et al. (1989). "Analysis of any point mutation in DNA. The amplification refractory mutation system (ARMS)." <u>Nucleic Acids Res</u> 17(7): 2503-16.		
	C14	Nikiforov, T. T., R. B. Rendle, et al. (1994). "Genetic Bit Analysis: a solid phase method for typing single nucleotide polymorphisms." <u>Nucleic Acids Res</u> 22(20): 4167-75.		
	C15	Orita, M., Y. Suzuki, et al. (1989). "Rapid and sensitive detection of point mutations and DNA polymorphisms using the polymerase chain reaction." Genomics 5(4): 874-9.		
	C16	Orita, M., H. Iwahana, et al. (1989). "Detection of polymorphisms of human DNA by gel electrophoresis as single-strand conformation polymorphisms." Proc Natl Acad Sci U S A 86(8): 2766-70.		
	C17	Orum, H., P. E. Nielsen, et al. (1993). "Single base pair mutation analysis by PNA directed PCR clamping." Nucleic Acids Res 21(23): 5332-6.		
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	C20	Syvanen, A. C., K. Aalto-Setala, et al. (1990). "A primer-guided nucleotide incorporation assay in the genotyping of apolipoprotein E." Genomics 8(4): 684-92.		
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	C23	Wagner, R., P. Debbie, et al. (1995). "Mutation detection using immobilized mismatch binding protein (MutS)." Nucleic Acids Res 23(19): 3944-8.		
	C24	Wallace, R. B., J. Shaffer, et al. (1979). "Hybridization of synthetic oligodeoxyribonucleotides to phi chi 174 DNA: the effect of single base pair mismatch." Nucleic Acids Res 6(11): 3543-57.		
-×-	C25	Youil, R., B. W. Kemper, et al. (1995). "Screening for mutations by enzyme mismatch cleavage with T4 endonuclease VII." Proc Natl Acad Sci U S A 92(1): 87-91.		

Examiner Signature	Date Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.

Include copy of this form with next communication to applicant.

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